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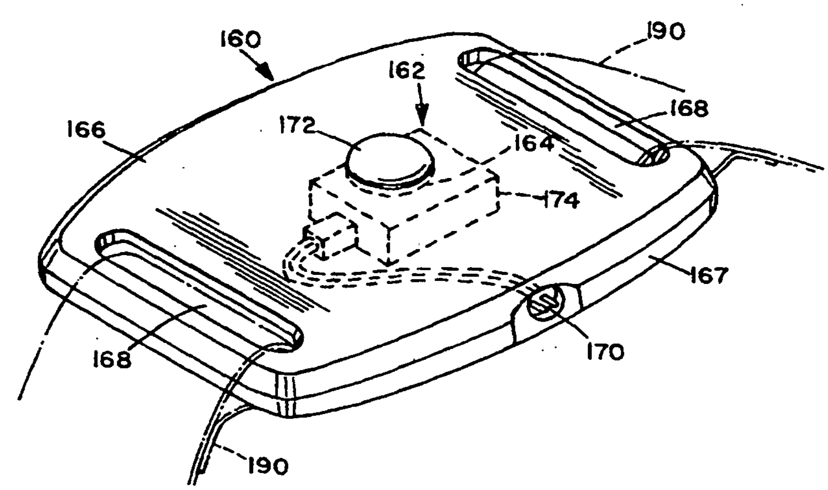
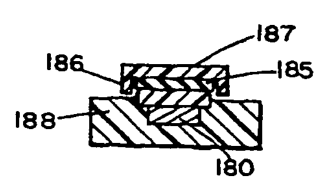
(54) Title: EMBEDDED SEMICONDUCTOR PRESSURE SENSORS, TOCODYNAMOMETERS

(57) Abstract

An embedded semiconductor pressure sensor for externally sensing he pressure within a body is disclosed. The pressure sensor includes a pliable housing (166) which substantially conforms to the body when pressed against the body by, for example, a belt secured through slots (168, 169) passing through the housing. A button (172) protruding from an exterior surface of the housing transfers force from the exterior surface to an interior cavity when the housing is pressed against the body. A solid state force sensor is located within the interior cavity of the housing adjacent to the button. The solid state force sensor receives the transferred force, detects the force, and generates an electrical signal representative of the force. Thus, the pressure sensor generates an electrical signal representing the pressure within the body. The solid state force sensor is sealed within the solid housing to provide environmental protection. The solid state force sensor (180) includes a piezoresistive integrated circuit which generates an electrical force signal when deformed by the force being measured. The integrated circuit is encased within a package having a movable piston (186) which tranfers the force from the button to the integrated circuit. A protective disk (187) and a spring (185) disposed over the movable piston provide further protection for the sensor. The pressure sensor can be used, for example, as an intra–uterine pressure sensor for generating electrical signals indicative of contractions during labor.





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EMBEDDED SEMICONDUCTOR PRESSURE SENSORS, TOCODYNAMOMETERS

FIELD OF THE INVENTION

The invention generally relates to the field of pressure sensors, and specifically to a pressure sensor including a solid state force sensor embedded within a protective housing which senses a force received from the exterior surface of the housing when the housing presses against a body.

BACKGROUND OF THE INVENTION

A normal labor process is divided into three stages. Among these stages, the first and second stages are the crucial ones which are directly involved in the delivery of fetus. The first stage of labor begins with the onset of rhythmic uterine contraction and ends at the complete dilation of the cervix which is about 10 cm in diameter. The complete dilation of the cervix marks the beginning of the second stage of labor which ends immediately after the birth of the fetus. The third stage of labor extends from the birth of the baby to the complete expulsion of the placenta. The labor progress is driven by two types of labor forces. The primary force is produced by the involuntary contractions of uterine muscle. The secondary force is produced by the increase of intra-abdominal pressure through voluntary contractions of the abdominal muscles and diaphragm. These forces cause an increase of intrauterine pressure to provide a critical expulsion force on fetus.

As often seen in clinical practice, systemic analgesic drugs, epidural anesthesia and long duration of exhaustive labor all can lead to the weakening of secondary force, and sequentially to delayed labor duration or even dystocia (arrest of labor). Numerous clinical studies have correlated a prolonged labor duration and dystocia with many undesirable outcomes, such as higher rate of infant mortality, neonatal seizures and postpartum hemorrhage. To solve these serious problems, clinical instruments (forceps or vacuum suction) or cesarean section are often required to terminate labors. However, both instrumental delivery and cesarean section are far from trouble-free. While a cesarean section is basically safe, it remains a

major surgical procedure. Patients who give birth by cesarean section are at much greater risk of childbirth-related illness or death than women who deliver vaginally. Also, the average cesarean birth has a length of hospital stay double that of a normal delivery and costs up to three times as much. The higher costs associated with cesarian delivery have received greater attention due to the growth of managed care. Because third party payor payments for hospital services are often a flat fee, hospitals are motivated to reduce the duration of hospital stays and the need for operating room personnel to reduce hospital costs and increase profits. Instrumental delivery also has limitations and may result in numerous complications including head and facial injuries to fetus. Therefore, it is in the best interest of both mother and fetus to prevent the incidence of prolonged duration of labor or dystocia.

One method of decreasing the incidence of prolonged labor is oxytocin infusion, which is commonly used in clinical practice to increase the primary labor force by directly inducing uterine contraction. Other pharmaceutical methods of induction are known, including the use of dinoprosten and progesterone antagonist (RU-486), however, oxytocin has been found to have the fewest adverse side effects. Clinical evidence has demonstrated that oxytocin alone can only partially solve the problem of prolonged labor and dystocia associated with epidural anesthesia. However, a high incidence of cesarean section still occurs in patients receiving epidural anesthesia in spite of a high dosage of oxytocin infusion. If the onset of labor is induced using oxytocin because spontaneous labor has not occurred, there is actually an increased cesarean risk compared with patients who labor spontaneously. Furthermore, high doses of oxytocin have been implicated in uterine tetanus and in some adverse neonatal outcomes, including fetal asphyxia. Therefore, continuous fetal monitoring is necessary when pharmaceuticals are used for uterine hyperstimulation to monitor the fetal response to labor and the uterine response to the inducing agent.

Devices directed toward assisting in delivery are disclosed in the prior art. In the apparatus of Heidenwolf (U.S. Patent No. 2,597,637, issued May 20, 1952), an inflatable bladder is held against the woman's upper abdomen by a wide belt. Extending from the bottom of the belt is a pair of straps

which, in turn, attaches to straps surrounding the upper thighs. This structure holds the belt down to prevent slippage.

In the birth-assisting pneumatic cuff of Lee (U.S. Patent No. 5,174,281, issued December 29, 1992), an inflatable bladder fits over and around the woman's abdomen and is manually inflated and deflated in coordination with the patient's voluntary muscle contractions during the second stage of labor. This device applies pressure equally to the entire abdomen.

The Chinese patent of Fei Chao (Chinese Patent No. 2198, issued in 1989) teaches an abdominal girdle which has a generally triangular bladder (to match the rough contour of the uterus) which is placed over the patient's abdomen. The bladder is inflated manually in coordination with the woman's contractions to apply a downward pressure on the abdomen, assisting in forcing the fetus downward. While the girdle itself is very effective, the manual control of the inflation/deflation may not be easily accepted by physicians who may be reluctant to rely on a device which could be easily subject to human error with serious consequences.

Related prior art may be seen in the areas of anti-G pressure suits and in inflatable tourniquets and splits. Examples of pressure suits are taught by Crosbie et al. in U.S Patent No. 4,534,338, issued August 13, 1985, and Van Patten, U.S. Patent No. 4,736,731, issued April 12, 1988. These suits inflate in response to changes in the rate of acceleration of an aircraft. Poole, et al. (U.S. Patent No. 4,531,516, issued July 30, 1985), Manes (U.S. Patent No. 4,548,198, issued October 22, 1985) and Kitchin et al. (U.S. Patent No. 4,520,820, issued June 4, 1985) teach inflatable devices for first aid applications. The latter two patents include disclosure of controllers for maintaining constant pressure, however none of these patents addresses synchronization of inflation/deflation as would be required for a labor- and delivery-assisting device.

Detection of intrauterine contractions for use with labor assisting devices, and for general monitoring of labor is commonly performed using a tocodynamometer or tocotransducer. Tocotransducers can sense uterine activity externally and non-invasively by measuring the hardness of the abdominal wall. They are held in place by a belt-like device which holds the sensor in the vicinity of the fundus (the top of the uterus). Use of such

devices has been reported since the 1930's, and the general configuration of the tocotransducers has changed little since the 1950's. The guard-ring tocodynamometer which was developed in the 50's by Smyth, et al., includes a resistance strain gauge supported within a rigid ring. This device has been identified as the only pressure sensor that externally provides an absolute estimation of the intra-uterine pressure. (See, e.g., C. Sureau, et al., Chapter 61, "Electronics and Clinical Measurement" in Obstetrics and Gynaecology, Elsevier Press (U.K.),1983.) The ring of the tocotransducer is pressed against the skin to flatten it, thus providing a fixed area of contact for the strain gauge. Increases in intra-uterine or intra-abdominal pressure, depending on placement, cause the skin area within the cavity formed by the ring to press against the strain gauge, providing the pressure reading. The skin area which must be covered in order to obtain reasonable accuracy with the tocotransducer is fairly large -- on the order of 50 cm^2 or more, and a considerable amount of pressure must be exerted on the ring to flatten the area completely. During labor, multiple sensors are usually placed on the patient's abdomen, e.g., for measuring intra-uterine pressure, fetal heart rate and fetal movement. The belts used to hold the rigid sensors in position must be wide and tight enough to provide stability. This increases patient discomfort, and the abdominal area can quickly become covered with various monitoring devices, so that it may become difficult to place every sensor at its ideal position, detracting from the accuracy of the monitoring. Further, existing tocotransducers are sensitive to environmental factors such as humidity and temperature, requiring frequent calibration, and have limited force ranges and maximum tolerances, such that the sensors can become saturated, or even be subject to failure, if not properly positioned and tensioned against the patient's skin. For example, a commonly-used tocotransducer sold by Hewlett-Packard has a maximum tolerance of about 1 kilogram (2.2 pounds) before failure. A similar device sold by Huntleigh has a range of approximately 100 grams and a maximum tolerance of about 320 grams (0.7 pounds).

General sensor technology has improved with developments in microelectronics, and semiconductor-based pressure sensors have been developed and made commercially available. One such solid state force sensor is marketed as the SenSym FS01 Series made by Kavlico Corporation

of Moorpark, California. The devices are low-cost piezoresistive integrated circuits encased within a plastic housing. The integrated circuit structure and process for making the circuit are disclosed in U.S. Patents 5,578,843 and 5,576,251, of Garabedian, et al., the disclosures which are incorporated herein by reference.

Briefly, the semiconductor sensor of Garabedian, et al. utilizes conventional MOS (metal-oxide-semiconductor) fabrication techniques to form MOGFETs (MOving Gate Field Effect Transistors) and MOPCAPs (MOving Plate CAPacitor). A flexible gate structure in the transistor spans a cavity, the bottom of which is an active region. Flexion of gate structure due to external pressure modifies the channel length to provide an electrically measurable change. In the capacitor, the top plate spans a cavity, the bottom of which is the other plate. The capacitance varies with flexion of the top plate, which variations are detected.

Another solid state pressure sensor is disclosed in U.S. Patent No. 5,113,868, of Wise, et al. This sensor is "ultraminiature" and is designed for use medical application for use in catheters and implantable devices. Such devices are very small, intended to detect minute variations in pressure with a small range, and are costly to manufacture.

BRIEF SUMMARY OF THE INVENTION

It is an advantage of the present invention to provide an improved pressure sensor for externally sensing the pressure within a body.

It is another advantage of the present invention to provide an embedded semiconductor pressure sensor for externally sensing pressure.

It is still another advantage of the present invention to provide an embedded semiconductor pressure sensor including a pliable housing which deforms to the body being monitored for improved accuracy.

Yet another advantage of the present invention is to provide an inexpensive yet robust pressure sensor which is protected against environmental factors such as humidity and from damage caused by mishandling or dropping the sensor.

Still another advantage of the present invention is to provide an improved tocotransducer for monitoring uterine contractions during labor.

In an exemplary embodiment, an embedded semiconductor pressure sensor for externally sensing the pressure within a body includes a housing having an exterior surface and an interior cavity. Means disposed on the exterior surface of the housing transfers force from the exterior surface to the interior cavity when the housing is pressed against the body. A solid state force sensor is located within the interior cavity of the housing adjacent to the means for transferring force. The solid state force sensor receives the transferred force, detects the force and generates an electrical signal representative of the force.

In another embodiment, an embedded semiconductor pressure sensor for externally sensing the pressure within a body includes a housing having an exterior surface, an interior cavity and means for attaching a pressure-applying device. The housing is formed from a pliable material so that the housing substantially conforms to the body when pressed against the body by the pressure-applying device. A button disposed on the exterior surface of the housing transfers force from the exterior surface to the interior cavity. The button is positioned to press against the body when the housing is pressed against the body. A solid state force sensor located within the interior cavity adjacent to the button is encased within a package having a movable piston in communication with the button to transfer force from the exterior surface to the solid state force sensor. The force sensor detects the force and generates an electrical signal corresponding to the force.

In yet another embodiment, an intra-uterine pressure sensor generates an electrical signal indicative of a contraction in a patient for use with a controller for regulating air pressure in an inflatable girdle for supplementing secondary labor force. The pressure sensor includes a housing formed from a pliable material which has an exterior surface and an interior cavity. Means disposed on the exterior surface of the housing transfers force from the exterior surface to the interior cavity. A solid state force sensor is embedded within the interior cavity adjacent to the means for transferring force for receiving the transferred force. The force sensor has a piezoresistive means for detecting the force and generating an electrical signal corresponding to the force. The pressure sensor further includes means for applying pressure to the housing so that the pliable material deforms to substantially conform to the patient's abdomen.

BRIEF DESCRIPTION OF THE DRAWINGS

Understanding of the present invention will be facilitated by consideration of the following detailed description of a preferred embodiment of the present invention, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts and in which:

Figure 1 is a block diagram of function of the childbirth assisting system of the present invention;

Figure 2 is a plot of pressure versus contraction duration;

Figure 3 is a block diagram of the components of the invention;

Figure 4 is a block diagram of the pressure feedback loop of the prototype system;

Figure 5 is a diagrammatic front view, partially cut away, of a first embodiment of the girdle for use with the present invention;

Figure 6 is a side elevation of a second embodiment of the girdle;

Figure 7 is a diagrammatic front view of a third embodiment of the girdle;

Figure 8 is a perspective view of a fourth embodiment of the girdle;

Figure 9 is diagrammatic side elevation of an alternate embodiment of the bladder/sensor combination;

Figure 10 is an exemplary plot of an indication of backpressure for assuring single use;

Figure 11 is a perspective view of a solid state tocotransducer for use in detecting intra-uterine pressure;

Figure 12 is a circuit schematic of an equivalent circuit for the piezoresistive force sensor for use in the solid state tocotransducer;

Figure 13 is a diagrammatic view of the piezoresistive force sensor for use in the solid state tocotransducer; and

Figure 14 is a cross-sectional view taken along line 14-14 of Figure 13.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Figure 1 is a block diagram of the childbirth assisting device including a patient and a uterine contraction monitor 2. A closed loop system uses

patient response and rule-based decision making methods to achieve operator specified responses. The inventive device is a pneumatic closed loop system which is composed of an abdominal girdle 3 and a controller 1. The controller 1 possesses five main functions:

1. Receiving the uterine activity data from the uterine contraction monitor 2 and detecting the onset and offset of contractions.
2. Synchronizing the girdle pressure with the contraction, increasing the girdle pressure at the onset of contraction and decreasing it at the offset of contraction.
3. Adjusting the girdle pressure automatically to obtain the intrauterine pressure at a preset level.
4. Displaying information, including the girdle pressure.
5. Setting an alarm or alert system for abnormal situations.

The uterine contraction activity can be monitored either internally or externally. Internal pressure monitoring provides the most accurate assessment of uterine activity by allowing pressure changes in the uterus to be transmitted via a fluid-filled catheter to a strain gauge transducer. This produces quantitative readings of the duration, frequency, and amplitude of the uterine contraction, as well as the baseline tone of the uterus. An external tocodynamometer can be applied easily at any stage of labor to provide a non-invasive method of assessing uterine contractions. This yields a good estimate of frequency of the contractions but a less accurate indication of the beginning, end and duration of the contraction, and the intensity. The actual amplitude of the contraction is difficult to measure by this method using conventional tocotransducers. For actual amplitude measurement an internal pressure monitor 2 may be used. The internal pressure monitor provides the accurate intrauterine activity data to the controller, which are necessary for improving the safety and efficiency of inventive device.

In the preferred embodiment, intra-uterine pressure monitoring is externally provided by a solid state force sensor embedded in a solid housing, as shown in Figure 11. The tocotransducer 160 includes force sensor 162

with a force-transferring face 164 which is positioned on housing 166 so that force can be transferred to the force sensor 162 when the monitor is in position.

Force sensor 162 is a piezoresistive semiconductor device constructed in accordance with the disclosure of U.S. Patents 5,576,251 and 5,578,843. These devices are sold commercially under the trade name SenSym. An equivalent circuit of the SenSym force sensor is provided in Figure 12, which shows the actual integrated circuit sensor element 180, the compensation network 182 and amplifier 184. External force is transferred to sensor element 180 by a piston 186 built into plastic package 188, as shown in Figures 13 and 14. Face 164 is positioned adjacent to the interior surface of the housing so that the external force can be transferred to piston 186. In order to protect the transducer from overload, a spring 185 and protective disk 187 are located over piston 186 so that they are in constant contact with each other. Protective disk 187, which provides the contact point for transfer of force from button 172 to sensor element 180, is substantially rigid, and may be formed of metal or a rigid plastic similar to that used for package 188. Spring 185 may be a conventional compression spring, or may be formed from a compressible, resilient elastomer which may be attached via an adhesive or other attachment means, or pre-loaded to the bottom of protective disk 187 and to the outer face of piston 186. Button 172 is made of the same material and molded at the same time as the housing, or may be rigid plastic attached via adhesive or other attachment means to the outer surface of the housing.

In the preferred embodiment, the force sensor 162 has a range of 800 grams with a maximum tolerance of 1.8 kilograms (4 lbs). These devices are accurate and stable over a 5-50 degree C temperature range. The 5V operating voltage for the force sensor may be provided by a single D.C. power supply up to +12V.

Force sensor 162 is completely embedded within housing 166, which is preferably an elastic and pliable elastomer. In the preferred embodiment, silicone having a Shore hardness of about 60 durometer is used. Other soft rubber-like materials may also be used. Housing 166 may be molded in two parts, top portion 167 and bottom portion 169. In top portion 167, a cavity 174 with a channel for a connection wire is formed on its inside surface for

receiving the sensor. Cavity 174 should be dimensioned to closely fit the exterior of force sensor 162 so that it is firmly held in place. Alternatively, a filler such as potting material may be used to hold the sensor within the cavity. Bottom portion 169 has a protruding button 172 on its exterior surface at a position corresponding to the location of face 164 when force sensor 162 is in place. Button 172 contacts the patient's abdomen and transfers force from the abdomen to face 164 for detection by force sensor 162.

Although button 172 is preferably semi-spherical to provide a focusing function, other shapes may be used as well. The size of button 172 has been determined to have an effect on the performance of the device. Tests were performed comparing a small button (15 mm (0.6 in.) dia. x 6 mm (0.25 in.) high), a medium button (17 mm (0.7 in.) dia. x 7 mm (0.28 in.) high), and a large button (24 mm (0.93 in.) dia. x 9 mm (0.32 in.) high), each being semi-spherical. While the large button had greater sensitivity, the small button exhibited the lowest signal-to-noise ratio (SNR). (SNR was determined by calculating the power spectrum of collected signal data, integrating the power spectrum over 60 seconds (signal) and dividing by the integral of the power spectrum under 60 seconds (noise).) The small button was also found to be most comfortable to the patient.

Force sensor 162 is sealed within the housing by vulcanizing or otherwise attaching top portion 167 to bottom portion 169. Connector 170 is protected during the assembly process so that, after the housing is sealed, it remains accessible for attachment of a cable connection to the monitor/controller. By completely sealing the sensor within housing 166, it is isolated from environmental factors, such as humidity which effect the performance of traditional tocotransducers, and is protected from damage caused by mishandling or dropping the device. In addition to the protection provided by housing 166, the package 188 of the force sensor itself provides corrosion resistance and isolation from external package stress, making the solid state tocotransducer robust.

An exemplary size for housing 166 is approximately 10.2 cm (4 in.) wide by 7.62 cm (3 in.) high by 1.3 cm (0.5 in.) thick (1.9 cm including button 172.) Housing 166 should be sufficiently pliable to conform to the patient's abdomen. This enhances the comfort as well as assuring that the

button 172 is uniformly pressed against the abdomen. A belt 190 (indicated with dashed lines) is used to hold housing 166 in position. Slots 168 are provided on the sides of housing 166 through which the belt is fastened. The belt may be nylon webbing or a soft, elastic fabric to enhance patient comfort, and may be attached by conventional fasteners such as buckles, snaps, or hook-and-pile fasteners. The forces applied by the belt inserted through slots 168 allow housing 166 to flex to conform to the patient's abdomen to facilitate uniform application of pressure. The relative thinness of the housing 166 compared with prior art tocotransducers provides the option, if necessary, of locating the contraction sensor beneath the girdle of the labor assisting system (between the girdle and the abdomen) without significantly compromising the patient's comfort. The need to position the sensor directly over the fundus for greatest accuracy is sometimes complicated by the size and weight of both the patient and the fetus, and such flexibility in placement of the sensor is advantageous.

Depending on the flexibility of the housing material, it may be desirable to include a stiffening material around the perimeter of housing 166 and slots 168, since excessive flexibility may damage the seal between sensor 162 and housing 166, or may actually cause sensor 162 to break. An exemplary material is a metal wire or band, or plastic bars, bands, or strands, which are flexible to a lesser degree that the housing material itself. This stiffening material is preferably embedded in one or both halves during the molding process and, thus, will not be visible, leaving a smooth exterior surface.

The solid state tocotransducer used in conjunction with the inventive system provides a number of advantages over conventional tocotransducers, including accuracy, robustness, durability and patient comfort. In addition, the solid state tocotransducer is likely to cost less than the widely-used guard ring tocotransducers due to the decreased labor costs for manufacture.

As an alternative to a closed loop system, the inventive system may operate on an open loop principle which comprises a modification of functions 2 and 3 listed above. In the open loop system, application and release of girdle pressure need not rely on intrauterine pressure. Instead, application of pressure to the girdle will be triggered by detection of contraction pressure by the external toco sensor only, and only after a pre-determined threshold pressure is attained and held for a specified period of

time. Once inflated, the girdle pressure is maintained for a fixed duration, e.g., 30 seconds, after which the release valve is automatically opened to deflate the girdle. The embodiment of Figure 4 is an exemplary open loop system.

The normal uterine contraction curve is bell-shaped, as shown in Figure 2, with the descending limb returning to the same basal level as preceded the ascending limb. At the beginning of the first stage of labor with cervical dilation up to 3 cm, an average increase in maximum uterine pressure above basal level is about 20 - 30 mmHg while at the active phase, with cervical dilation from 3 cm to 10 cm and the second stage of labor, it is in the range of 40 - 50 mmHg. Contraction frequency also increases from two to three per 10 minutes to four to five per 10 minutes at the end of labor. On slow rise of uterine pressure, the controller evaluates the uterine activity data and determines the onset of contraction. Once the controller 1 detects the onset of contraction, the girdle pressure will be increased. Determining the onset of contraction is somewhat arbitrary. This invention may not be recommended for use during the early first stage of labor including the early active phase (cervical dilation up to 6-7 cm). In the preferred embodiment, the onset of contraction is set at 15-20 mmHg above the basal level. At the onset of contraction, the girdle pressure is increased at the preset rate until the preset intrauterine pressure is obtained. Once the intrauterine pressure reaches the preset pressure, the girdle pressure will be maintained to obtain a constant intrauterine pressure. The offset of contraction can be detected when the girdle pressure increases sharply, as shown in Figure 2. The girdle pressure will be released upon detection of the offset of contraction.

The girdle 3, illustrated in detail in Figure 5, is formed of two basic components: the belt 100 and the bladder 102. The design of the belt requires two considerations. The inner lining must be soft and comfortable to the mother while the outer lining must have high tensile strength so that it can be tightly secured around the mother to keep the bladder inflation pressure downward against the abdomen. The belt 100 may be formed from polyvinyl chloride (PVC) or an elastomer-coated fabric, such as polyurethane-coated nylon. For the patient's comfort, the interior lining of the belt which comes in contact with the skin should be a soft fabric, such as the loop material of a hook-and-loop fastener, velour, woven fabric such as cotton or

nylon, netting, or a combination of materials including a laminate. The choice of materials will depend on the integration of the bladder. For example, the belt could serve as the reinforced lining to the bladder, or it could be part of the bladder. An elastomer coating on outer layer of the belt may be added to prevent the fabric from stretching, or the outer surface may be non-stretch cotton fabric or surgical tape. In one version illustrated in Figure 5, the belt is originally formed in two layers 101 and 103 so that the bladder 102 may be inserted between the layers. (Layer 101 represents the outer PVC layer and layer 103 represents the inner fabric-lined layer.) The layers may be sealed together after the bladder is inserted to firmly retain the bladder at a fixed position within the belt. The sealing welds 105 are indicated as dashed lines. Alternatively, the bladder 102 may be floating, sealed to only one of the two layers of the belt, or unattached to either layer and simply retained between the two layers once they have been sealed together. Selection of belt configuration may be made based upon pressure transfer efficiency, with the floating bladder version having demonstrated improved pressure transfer in prototypes of the invention. The choice of material of which the belt is made will depend upon whether the bladder is attached or floating.

In another embodiment shown in Figure 6, the inner and outer layers 101' and 103' are sealed together without placing the bladder between the layers. The bladder 102 is held directly against the mother's abdomen, with the inward force of the belt providing means for maintaining the bladder in the proper location.

Belt tension is critical to the performance of the belt. In order to facilitate the best possible fit to the mother, the end of the belt may be split to form two separately adjustable straps 104 and 106, as shown in Figure 5. Strips of Velcro®, or a similar hook-and-pile fastener 110, are sewn onto end 108 of the belt and onto the ends of straps 104 and 106. The split design allows for the closest possible fit. The fastener on straps 104 and 106 should have sufficient length to adjust the belt diameter as needed for a particular patient. In order to optimize the fit of the belt, finger loop 109 is formed in end 108 to provide an anchor for medical personnel to use while pulling the straps to the desired tension. The loop 109 may be formed by doubling over a small portion of the belt material, then welding it in place.

Due to the significant amount of monitoring equipment that is used during a delivery, it may become difficult to place certain sensors on the patient's abdomen in conjunction with the belt 100. One method for alleviating this is by providing tabs 112 and 114 at the lower edge of the belt 100 which permit attachment of the toco sensor directly to the belt, eliminating the need for an additional toco belt. The toco sensor 116, which monitors the contractions, may be mounted on an elastic fabric 118 with eyelets 120, 121, adhesive strips, hook-and-pile fasteners or snaps at either end which attach to corresponding fasteners 122, 123 on tabs 112, 114. With a standardized length between the eyelets 120, 121, since the tabs 112, 114 are at a fixed distance (17.5" in the preferred embodiment), this provides a further advantage in that the toco sensor is always maintained at the same tension against the mother's abdomen. Alternatively, for use with the tocotransducer of Figure 10, adjustable straps may extend inward from tabs 112, 114, the width of the straps being adapted for insertion through slots 168.

The expandable bladder 102 may be formed from a thin reinforced polyurethane, polyvinyl chloride (PVC), silicone, or similar elastomeric membrane material. In the embodiment of Figure 5, the bladder is sandwiched between and welded to the belt material so that the bladder cannot move within the belt. Inflation nipple 128 extends from bladder 102 through an opening in the belt 100. The material of which the preferred embodiments of the belt and bladder are made are selected to permit the girdle to be economically manufactured as a single-use, disposable item. For safety reasons, to assure that the girdle is not weakened or degraded by multiple uses, the inflation nipple 128 can include means for assuring that a girdle is used only once. The single use means can be a break seal/plug incorporated into the inflation nipple 128 which, once connected to the monitor and air supply hoses must be broken to remove it, preventing its reuse. Other means for assuring single uses of the girdle can be a peel away connector in the inflation nipple 128, a piezo film, or a rupture film built into the nipple 128. The rupture film 129 (shown diagrammatically as dashed lines in Figure 5) spans the interior of the nipple 128 and works in cooperation with the controller 1. When the air supply hoses 24A and 24B are connected to the girdle (referring to Figure 3), an initial burst of air can

be provided to rupture the film 129. The sense valve 9 will detect a backpressure and the controller 1 will have stored data regarding a pre-set pressure threshold value at which rupture of the film should occur. If the threshold backpressure is not attained, this may be an indication that the film 129 was already ruptured in a previous use of the girdle. Software within the controller 1 will prevent any further use of the system until a new girdle is detected by way of the proper backpressure. An exemplary plot of detection of a seal by backpressure showing hypothetical upper and lower limits (UL and LL) for as thresholds for confirming correct backpressure and time to rupture is provided in Figure 10.

A piezo film would function in a similar manner, with the film, itself, providing the signal indicative of the pressure being applied during the initial burst. Alternately, an electrically conductive strip could be built into the nipple 128 which can be detected by causing a change in resistance of electrical wiring built into the air tubing.

An alternate solution to the problem of a limited area on the mother's abdomen on which a number of different devices need to be placed is to utilize the bladder 102 itself as part of the contraction sensor. This is favorable because the bladder membrane is sound sensitive and will conduct the acoustic waves for pick-up by a sensor 130 built into the bladder, as shown in Figure 6.

A second alternate solution to working within the limited space is to form the bladder with fan-folds 132 or accordion pleats, as illustrated in Figure 7. Here, when the bladder is deflated it covers only a small area of the abdomen. Upon inflation, the bladder expands within the belt into the area indicated by dashed lines 136 to apply pressure in the appropriate direction. A pocket within the belt controls the direction of expansion of the bladder to assure that the pressure is dispersed uniformly and in the proper direction. When the bladder is inflated, the readings from the toco sensor are not as critical, so expanding the bladder over the toco sensor is not a problem.

The girdle may also incorporate one or more separate bladders 140 which are controlled independently of the primary labor-assisting bladder 102 to regulate overall belt pressure and to add lumbar support. This embodiment is shown in Figure 8. Note that the primary bladder 102 is

shown in a slightly different configuration from the typical triangular shape. The shape of the primary bladder is not limited to a triangle, nor must the size be fixed. It can be varied as needed to apply the desired pressure appropriately. Secondary bladders 140 help reposition the patient during periods of discomfort. Inflation of bladders 140 can be coordinated with contractions to alleviate lower back pain associated with the contractions, or inflation can simply occur at fixed intervals to provide a massaging function. Bladders used for regulating belt tension can alleviate pressure from the epidural and spinal column, making belt application easier.

The sensor for detecting contraction and fetal heartbeat may be incorporated into the girdle as described above in the form of a toco sensor, or may utilize ultrasound, pressure sensitive ink or piezo film 150, which may be incorporated into the fabric of the belt or in the bladder 152 (see Figure 9), or air/fluid displacement. The piezo film 150 may be polyvinylidene fluoride (PVDF), which transducers are known in the art. A representative discussion of such transducers for fetal heart sound detectors and uterine contraction monitors is provided in the article entitled "An Application of PVF_2 to Fetal Phonocardiographic Transducers", F. Steenkeste, *et al.*, "Proceedings of the First International Symposium on Piezoelectricity in Biomaterials and Biomedical Devices", Pisa, Italy, 20-22 June, 1983, published in *Ferroelectrics*, October 1984, Vol. 60, No. 1-4, pp. 93-98. Three approaches for placement of the sensor(s) are: multiple small pockets located below the main bladder, a Velcro®-backed sensor that can attach to a loop lining on or around the main bladder, or a sensor sealed inside the main bladder, such as shown in Figure 6. Multiple sensors may be used in series for greater reliability. Air pockets and bladders are ideal for housing small sensor because they can accurately and consistently apply the force necessary for reliable signal response, and they provide the direct capability to synchronize operations with the main bladder.

Figure 3 is a block diagram of automatic labor assisting device, showing the details of the controller 1 and the girdle 3 according to the present invention. Within controller 1, a pressure sensing means, including pressure transducer 11 and analog signal conditioner 12, produces a signal which is fed into the microprocessor 22. The signal is quantized in a 12 bit analog-to-digital converter within the microprocessor 22. A display means,

which includes a memory and signal processing circuitry within the microprocessor 22 and display 13, produces a pressure display of the girdle's internal pressure. A memory 40 within the controller provides storage for control parameters and a library of diagnostic information, which is described below in more detail. An inflatable girdle 3 is shown connected via tubing 24A and 24B to the controller 1 at coupling 25A and 25B. Coupling 25B is connected via valve 9 and pressure line 26 to pressure transducer 11. A signal representing the pressure measured by the pressure transducer 11 and analog signal conditioner 12 is applied via electrical line 27 to microprocessor 22. Two of the control switches 15 are used to apply a signal to microprocessor 22 to set a target intrauterine pressure and a maximum girdle pressure. A signal representing intrauterine pressure is applied to microprocessor 22 via connector 28 and electrical line 29.

Microprocessor 22 is programmed to calculate the girdle pressure adjustment proportional to the magnitude of the difference between the intrauterine pressure and the selected target pressure, and produces an output signal on line 30 which indicates the girdle pressure adjustment. A select switch in control switch 15 determines if an external air line via air line 42, an internal replaceable air bottle via air line 21, or an internal motor 5 and pump 6 are to be used to inflate the girdle. Note that all three air paths are isolated from each other via check valves 18, 19 and 32. The motor 5 is turned on and off by the microprocessor 22 via line 31 to a motor and valve driver circuit 4. The pressure to the girdle 3 is controlled by the regulator 17. Valve 7 vents the pressure in girdle 3 via vent 8 for a time determined by microprocessor 22 through line 52.

Power is applied to controller 1 through line 33 via switch 34 and circuit breaker 35. A voltage regulator 36 provides a 5 volt regulated voltage which is used to power the portion of the digital circuit requiring a positive 5 volts. The 12-volt voltage output is also provided for portions of the circuitry such as the valves, pumps and pressure transducer which require 12-volt power supply. Differential pressure switches 44 are connected between lines 37A and 38B. If any obstruction occurs between lines 37A and 37B, switches 44 apply a signal to microprocessor 22 through line 38 to sound an alarm.

The microprocessor 22 utilizes the information and the signals applied to it to control the girdle 3 and to provide information output. Signals applied from microprocessor 22 to the displays 13 and printer 16 include:

Target intrauterine pressure
Maximum girdle pressure
Current intrauterine pressure
Uterine pressure due to primary force
Current girdle pressure
Diagnostic information for doctor
Alarm for whether there is an obstruction (kink).

The microprocessor 22 compares the input signal received from the intrauterine monitor and the girdle pressure sensors against criteria which are stored in the memory 40. These criteria include the various pressure settings, as well as means for identifying the presence of abnormal contractions which may require modification of the operating parameters of the controller or may require removal of the girdle.

Signals are generated to sound alarm 14 whenever alarm conditions are met. The alarm may be silenced if desired via one of the control switches or by pressing an emergency stop button which will deactivate the controller and deflate the girdle. Sense valve 9 is connected between girdle 3 and pressure transducer 11. The sense valve 9 connects the pressure transducer 11 to atmosphere through vent 10 during the girdle start-up sequence in order to correct the pressure transducer zero offset. Overpressure valve 39 is connected to the line 50 between regulator 17 and inflate-deflate valve 7. This is a manually adjustable valve which limits the maximum pressure delivered to the girdle, in the event that all the safeguards in the air regulation line systems fail. In addition, safety valve 23 is designed into the girdle 3 to deflate the girdle in case of extreme overpressure which would endanger the fetus.

A prototype of the controller was designed with two feedback control loops. The first loop monitored and evaluated the activity of the uterine contraction. Intrauterine pressure was detected by a strain gauge operated with a bending beam mechanism. The output signal of the strain gauge

ranged from 1V at zero pressure to 5V at 105g of force. The signal generated by the strain gauge was digitized and transferred to the built-in microprocessor. The programming within the microprocessor caused the second feedback loop to be initiated once the intensity of the contraction reached a certain point (20% of full scale) and stayed over that point for 5 seconds. Using this criteria, a false signal generated by non-contraction processes such as physical movement by the patient could be filtered out.

The second feedback control loop, shown in Figure 4, controlled the inflation and deflation of the girdle 3 using an air compressor 60. This loop is a slight modification of the system of Figure 3. The girdle is connected to the air compressor 60 (Gast Manufacturing Corp. diaphragm compressor, 50 PSI maximum with 15 cubic inches per second air flow) through air line 80 with air valve 67 controlling the rate of inflation of the girdle 3. The girdle 3 may be deflated through air line 82 by opening air valve 77 and venting the girdle to atmospheric pressure. Each line is connected with its own transducer 72 or 76, each with an output of 1V per 100 mmHg (SenSym, output range of 1 to 15 volts with a base voltage of 1 volt at 0 mmHg). Transducer 76, attached to air line 82, reads the air pressure coming into the girdle from the air compressor. When the onset of contraction is detected and meets the true contraction criteria, air passes through air line 80 until the internal girdle pressure reaches the target belt pressure established by the operator. When the girdle pressure reaches its target, air valve 72 switches off to block the air flow into the girdle.

If the girdle pressure drops, transducer 76 detects the drop, and air valve 67 is activated to re-pressurize the girdle to target pressure. As a safety mechanism, valve 77 opens 30 seconds after initiation of the inflation process to deflate the girdle.

To detect the occurrence of tube kinking, the microprocessor sets a minimum pressure increase of 10 mmHg for 5 seconds. Any rates below this are treated as tube kinking, triggering immediate deflation of the girdle and activating an audible alarm for 5 seconds or longer. If this safety device fails, an emergency stop button is provided. The emergency stop button opens valve 77 and closes valve 67 for emergency deflation.

Displaying various forms of outputs is an important function of the controller 1. The girdle pressure and the patient information are displayed

on the screen. To detect hazardous conditions or unexpected patient responses, numerous alert and alarm criteria may be optionally implemented within the device control software:

1. Setting a maximum duration at the target intrauterine pressure during the contraction: A normal contraction may last about 60 - 90 seconds. However, abnormal contractions such as polysystole, skewed contractions and tachysystole may show a longer contraction period due to a slow return to a baseline. This may result in applying the high pressure onto the abdomen over an extended period. To avoid this problem, the maximum duration at the target intrauterine pressure during the contraction will be established at 20 - 60 seconds. In the prototype, the limit was set at 30 seconds.

2. Setting an interval between two cycles of girdle pressure increase: Contraction frequency increases from two to three per 10 minutes to four to five per 10 minutes at the end of labor. Abnormal contractions such as paired contractions show much a shorter interval between two contractions. The use of the labor assisting device in this case may result in applying an excessive force to the abdomen in a short time period. This problem will be solved by setting a minimum interval between two cycles of girdle pressure increase. The minimum interval will be set at 1.5 - 5 minutes, with the prototype set at 1.5 minutes.

3. Setting the target intrauterine pressures at different stages of labor: In normal labor, an average increase in maximum uterine pressure above basal level begins with about 20 - 30 mmHg at the early first stage of labor and becomes 40-50 mmHg at the active phase and the second stage of labor. This force is mainly produced by the primary and involuntary force. In addition to the primary force, the use of the inventive device will increase the intrauterine pressure further by providing the secondary force. To enhance the safety of the device, the target intrauterine pressures are assessed during various phases of labor. For example, the target intrauterine

pressure during the stage of labor with cervical dilation from 3 cm to 8 cm is set at 40 - 60 mmHg above the baseline while during the active phase with cervical dilation from 8 cm to 10 cm at 60 - 80 mmHg and the second stage of labor at 80 - 160 mmHg. The decision of whether the stage of labor is early or active should be made by a physician. Obstetricians also set up the appropriate target intrauterine pressure depending on clinical situations. Any uncontrollable intrauterine pressure increase above the target pressure (15 mmHg higher than the target) will trigger the alarm system and rapidly deflate the girdle.

4. Setting a limit of the girdle pressure at each target intrauterine pressure: This mechanism also prevents any extra force on the abdomen which may result from malfunctions of the device. For example, the limit of the girdle pressure will be set at 150 mmHg during the stage of labor with cervical dilation from 3 cm to 8 cm when the target intrauterine pressure is 40 - 60 mmHg. The limit will be set at 250 mmHg during the active phase of labor with cervical dilation from 8 cm to 10 cm when the target intrauterine pressure is 60 - 80 mmHg. The limit will be set at 350 mmHg during the second stage of labor. The girdle pressure above these limits triggers the alarm system and rapidly deflates the girdle. The girdle may also be implemented with its own safety valve which be blown if the pressure exceeds 350 mmHg. In the prototype, the safety valve was implemented by setting the maximum pressure of 350 mmHg in the controller software and by an inline air regulator 66 (in Figure 4). If the girdle pressure exceeded 350 mmHg, valve 77 opened to deflate the girdle.

5. Filtering the false contractions: The movement of patient sometimes generates the sudden rise of intrauterine pressure. This can be filtered by evaluating the rate of intrauterine pressure increase, defined as a derivative, dP/dt, where P = intrauterine pressure and t = time, and comparing with a normal range of the rate. Any contractions with the rate of

intrauterine pressure higher than the normal range will be treated as false contractions and will not trigger the inflation of the girdle.

In the prototype, a fault signal generated by non-contraction processes is filtered by setting a 5 second delay rule, i.e., a true contraction occurs if the intensity of the signal remains at 20% of full scale for 5 second.

For the safe use of the childbirth assisting device, several abnormal clinical situations have been considered. The criteria for each of these situations is stored within a library in the controller's memory 40 and the contraction data is compared against these criteria to determine whether the abnormal condition is present. If so, an alarm condition is initiated and an output is provided to indicate the presence of the abnormal condition. The following situations are included in the library of abnormal conditions:

1. Hypotonia/Hypocontractility:

When contractions are less than 25 to 30 mmHg at their peak, or recur less frequently than every five minutes in the active phase of labor and last less than 45 seconds, hypocontractility is present, even if it is accompanied by progress in labor. The decreased uterine activity may be due to the abnormal contraction, hypotonia, or the artifact from the presence of air in the internal monitoring system. In both cases, the use of the device may not cause safety problems. However, since the device will not allow the girdle pressure to exceed the safety limit, the alarm system will be on before the target intrauterine pressure is obtained. The correction should be made upon a proper diagnosis of the above problems. The presence of air in the internal monitoring system can be corrected easily and device can be restarted.

2. Polysystole:

Polysystole is a common abnormal uterine waveform that is characterized by a single contraction with two or more peaks. It is also described as two or more contractions in juxtaposition

without full return to the baseline between each. This could be determined by software and if the situation meets the alarm criteria set in the above section, the girdle should deflate and a physician should be informed.

3. Discoordinate uterine activity:

The constancy of the intervals between uterine contractions determines the degree of coordination or rhythm of uterine activity. When a marked variation occurs from contraction to contraction, the resultant pattern is termed "discoordinate labor". Because contractions may be generated from alternate uterine cornua as well as from other sites, frequent low intensity contractions are a typical finding. Since the controller sets up a threshold to evaluate the onset of contraction, some of the low-intensity contractions below this threshold may not trigger the girdle pressure to increase. This will be similar situation of hypotonia. In this case, the use of the device may not cause any safety problem. Other discoordinate labor, Uterine hypertonus, may result from the constantly contracting state of some area in the myometrium. Extreme degree of this phenomenon is uterine fibrillation. In this case, the use of the device should be avoided.

4. Skewed contractions:

A skewed contraction is characterized by a prolongation of the descending limb (relaxation phase) of the uterine contraction and is often seen in a mixed pattern with polysystole. The use of the inventive device implemented with a maximum duration at the target intrauterine pressure will not cause any problem.

5. Paired contractions:

Paired contractions are a form of increased uterine contraction frequently characterized by one uterine contraction in close temporal relationship to a second uterine contraction, with the waveform returning to baseline between the two contractions. Usually, the second contraction is smaller in amplitude. Since the device sets the minimum interval between

two cycles of girdle pressure increase, its use under this condition will not cause any safety problem.

6. Tachysystole:

Tachysystole is defined as increased uterine contraction frequency. Because of the inevitable accompanying diminished or absent resting interval, decreased fetal oxygenation has been associated more often with this form of uterine hyperactivity than with increased intensity or duration of the uterine contraction. However, increased uterine activity of any type does not infer fetal stress or distress. Increased uterine activity may well be tolerated by some fetuses, whereas others may demonstrate stress even with uterine activity of a low intensity. As long as the fetus does not show distress, the use of the inventive device will not cause any problem. The software in device will diagnose the situation. However, a physician should make a final decision.

7. Tachysystole with progressive hypertonia:

Progressive hypertonia, usually associated with tachysystole, is a form of uterine dysfunction. It represents incomplete relaxation between frequently occurring contractions. The software in the inventive device will diagnose the situation. However, a physician should make a final decision about continued use of the device.

8. Tachysystole with progression to tetany:

Progressive uterine hypertonus, characterized as a rising baseline tone, is often accompanied by tachysystole. During the relaxation phase, the uterine tone does not completely return to the prior resting phase level before the next contraction begins. This may progress to tetany. The software in the inventive device will diagnose the situation. The use of the device should be decided by a physician under this circumstance.

9. Peaked contractions:

A contraction pattern of high intensity and frequency, with a peaked contour, has been associated with preeclampsia

and eclampsia. The software in the labor assisting device will diagnose the situation. The use of the device should be decided by a physician under this circumstance.

10. Hypersystole:

The amplitude of intensity is the pressure difference (in mmHg) between the peak of the uterine contraction and the uterine tone preceding the contraction. Hypersystole is defined as greater than 60 mmHg maximum pressure. Contractions of greater than 60 mmHg are seen with pharmacologically overstimulated or spontaneous abnormal labor. If there is enough uterine pressure, the use of the device is not necessary. A physician will make a decision on continuing the use of the device.

The childbirth assisting device of the present invention effectively prevents prolonged duration of labor and dystocia due to systemic analgesia, epidural anesthesia, or maternal exhaustion, leading to reduction of the cesarean section rate and rate of instrumental delivery. Since weakening of the secondary labor force is particularly common in patients receiving epidural anesthesia, the device can effectively prevent weakening of the secondary labor force under anesthesia, enabling a safer and less painful delivery. The inventive device includes means for analyzing the contraction curve and period in order to identify the presence of abnormal conditions, providing further safety benefits.

Detection of intra-uterine pressure is enhanced by the use of a solid state pressure sensor, providing more accurate detection of contractions to facilitate synchronization of application of supplemental secondary force as well as to provide means for determining the presence of abnormal conditions.

By reinforcing the secondary labor force, the childbirth assisting device can further reduce the rate of cesarean section associated with dystocia and also lower the dosage of oxytocin. Functioning through different mechanisms, the device can be used to complement the benefits of oxytocin and other pharmaceutical induction methods in clinical practice.

Tocotransducer 160 is an embedded semiconductor pressure sensor which can be used or modified for use in other applications. Although the above description shows the pressure sensor pressed against the abdomen of a woman for monitoring contractions during labor, the pressure sensor can also be used for externally monitoring the pressure within other bodies which change shape in response to changing pressure. The hardness of housing 166 can be modified to accurately measure the pressure within the body being measured based upon the results of analytical tests using different housing materials. Although the use of a pliable housing material which conforms to the patient's abdomen increases the accuracy of the contraction monitor described above, a stiffer or non-pliable material may provide suitable accuracy for other applications.

It will be evident that there are additional embodiments and applications which are not disclosed in the detailed description but which clearly fall within the scope and spirit of the present invention. The specification is, therefore, not intended to be limiting, and the scope of the invention is to be limited only by the following claims.

WE CLAIM:

CLAIMS

1. An embedded semiconductor pressure sensor for externally sensing the pressure within a body, the pressure sensor comprising:

a housing having an exterior surface and an interior cavity;

means disposed on the exterior surface of the housing for transferring force from the exterior surface to the interior cavity when the housing is pressed against the body; and

a solid state force sensor located within the interior cavity of the housing adjacent to the means for transferring force for receiving the transferred force, the solid state force sensor being configured to detect the force and to generate an electrical signal representative of the force.

2. The pressure sensor of claim 1, wherein the housing is solid and the solid state force sensor is sealed within the housing so that it is isolated from the exterior surface of the housing.

3. The pressure sensor of claim 2, wherein the housing includes a top portion attached to a bottom portion, the interior cavity being formed between the top portion and the bottom portion.

4. The pressure sensor of claim 1, wherein the means for transferring force includes a button protruding from the exterior surface of the housing, the button being positioned to press against the body when the housing is pressed against the body.

5. The pressure sensor of claim 4, wherein the button has a semi-spherical shape.

6. The pressure sensor of claim 1, wherein the solid state force sensor includes a piezoresistive integrated circuit.

7. The pressure sensor of claim 6, wherein the solid state force sensor further includes an amplifier circuit which amplifies a force signal generated by the piezoresistive integrated circuit and a compensation circuit which generates a compensation signal applied to the amplifier circuit.

8. The pressure sensor of claim 6, wherein the integrated circuit is encased within a package having a movable piston for transferring the force from the means for transferring force to the integrated circuit.

9. The pressure sensor of claim 8, wherein the solid state force sensor further includes a resilient member and a protective disk disposed over the movable piston for preventing overload of the solid state force sensor.

10. The pressure sensor of claim 8, wherein the solid state force sensor further includes a protective disk and a spring disposed over the movable piston.

11. An embedded semiconductor pressure sensor for externally sensing the pressure within a body, the pressure sensor comprising:

a housing formed from a pliable material, the housing having an exterior surface, an interior cavity and means for attaching a pressure-applying device, wherein the housing substantially conforms to the body when pressed against the body by the pressure-applying device;

a button disposed on the exterior surface of the housing for transferring force from the exterior surface to the interior cavity, the button being positioned to press against the body when the housing is pressed against the body; and

a solid state force sensor located within the interior cavity of the housing adjacent to the button, the solid state force sensor being encased within a package having a movable piston in communication with the button to transfer force from the exterior surface of the housing to the solid state force sensor, the solid state force sensor being configured to detect the force and to generate an electrical signal corresponding to the force.

12. The pressure sensor of claim 11, wherein the pliable material is an elastomer.

13. The pressure sensor of claim 12, wherein the elastomer has a Shore hardness on the order of 60 durometer.

14. The pressure sensor of claim 11, wherein the housing is solid and the solid state force sensor is sealed within the housing so that it is isolated from the exterior surface of the housing.

15. The pressure sensor of claim 11, wherein the means for attaching a pressure-applying device includes first and second slots located at opposite sides of the housing for attachment to a belt.

16. The pressure sensor of claim 11, wherein the button has a semi-spherical shape.

17. The pressure sensor of claim 11, wherein the solid state force sensor includes a piezoresistive integrated circuit.

18. The pressure sensor of claim 11, wherein the solid state force sensor further includes a resilient member and a protective disk disposed over the movable piston for preventing overload of the solid state force sensor.

19. An intra-uterine pressure sensor for use in conjunction with a controller for regulating air pressure in an inflatable girdle for supplementing secondary labor force, the pressure sensor generating an electrical signal indicative of a contraction in a patient, the pressure sensor comprising:

a housing formed from a pliable material, the housing having an exterior surface and an interior cavity;

means disposed on the exterior surface of the housing for transferring force from the exterior surface to the interior cavity;

a solid state force sensor embedded within the interior cavity adjacent to the means for transferring force for receiving the transferred force, the solid state force sensor having a piezoresistive means for detecting the force and generating an electrical signal corresponding to the force; and

means for applying pressure to the housing so that the pliable material deforms to substantially conform to the patient's abdomen.

20. The pressure sensor of claim 19, wherein the pliable material is an elastomer.

21. The pressure sensor of claim 20, wherein the elastomer has a Shore hardness on the order of 60 durometer.

22. The pressure sensor of claim 19, wherein the housing is solid and the solid state force sensor is sealed within the housing so that it is isolated from the exterior surface of the housing.

23. The pressure sensor of claim 19, wherein the means for transferring force includes a button formed in the exterior surface of the housing, the button being positioned to press against the patient's abdomen.

24. The pressure sensor of claim 23, wherein the button has a semi-spherical shape.

25. The pressure sensor of claim 24, wherein the button has a diameter of less than 24 mm.

26. The pressure sensor of claim 24, wherein the button has a diameter on the order of 15 mm.

27. The pressure sensor of claim 19, wherein the solid state force sensor includes resilient means for preventing overload of the solid state force sensor.

28. The pressure sensor of claim 19, wherein the piezoresistive means is encased within a package having a movable piston for transferring the force from the means for transferring force to the piezoresistive means.

29. The pressure sensor of claim 28, wherein the solid state force sensor includes a protective disk and a spring disposed over said movable piston.

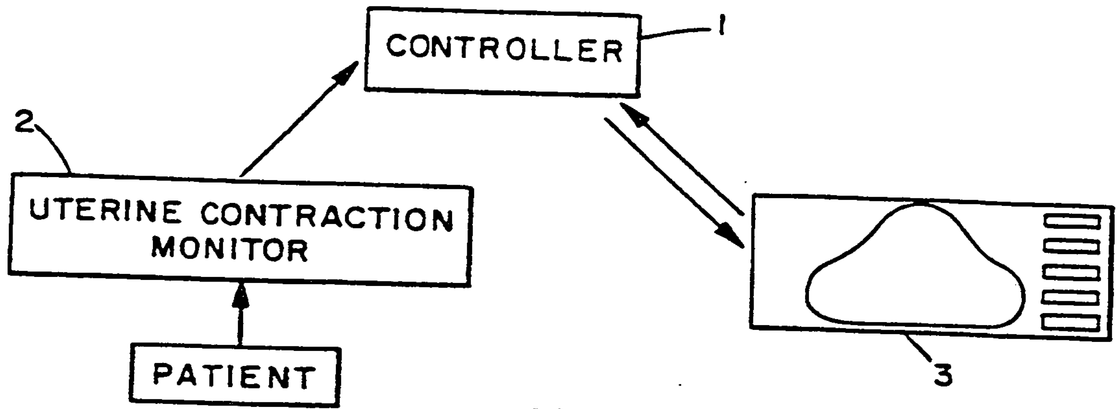

CONTROLLER
1
2
UTERINE CONTRACTION MONITOR
PATIENT
3

FIG. 1

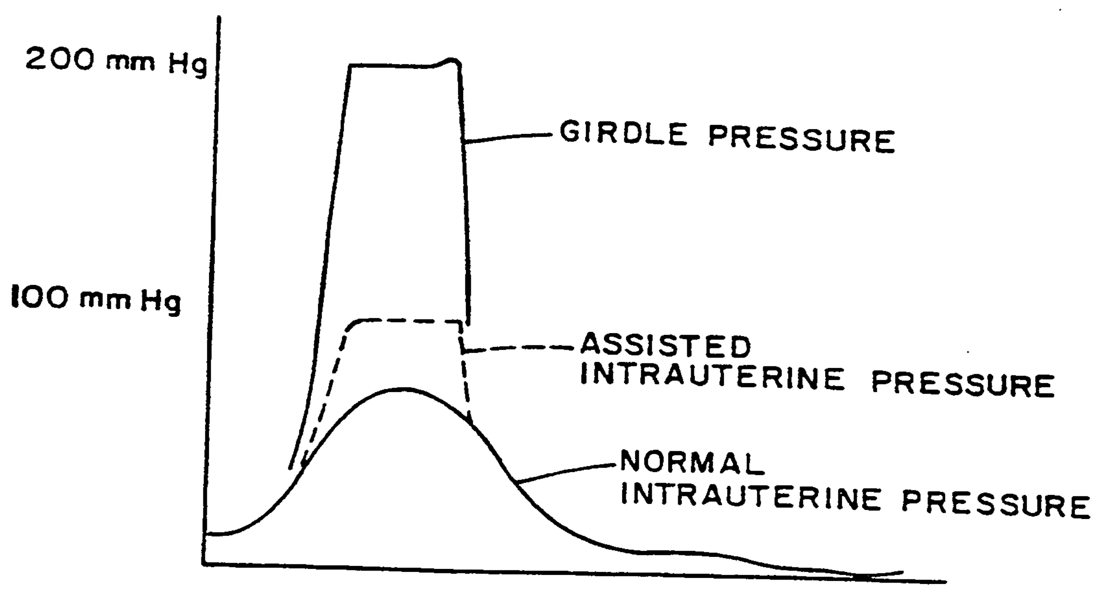

200 mm Hg
100 mm Hg
GIRDLE PRESSURE
ASSISTED INTRAUTERINE PRESSURE
NORMAL INTRAUTERINE PRESSURE

FIG. 2

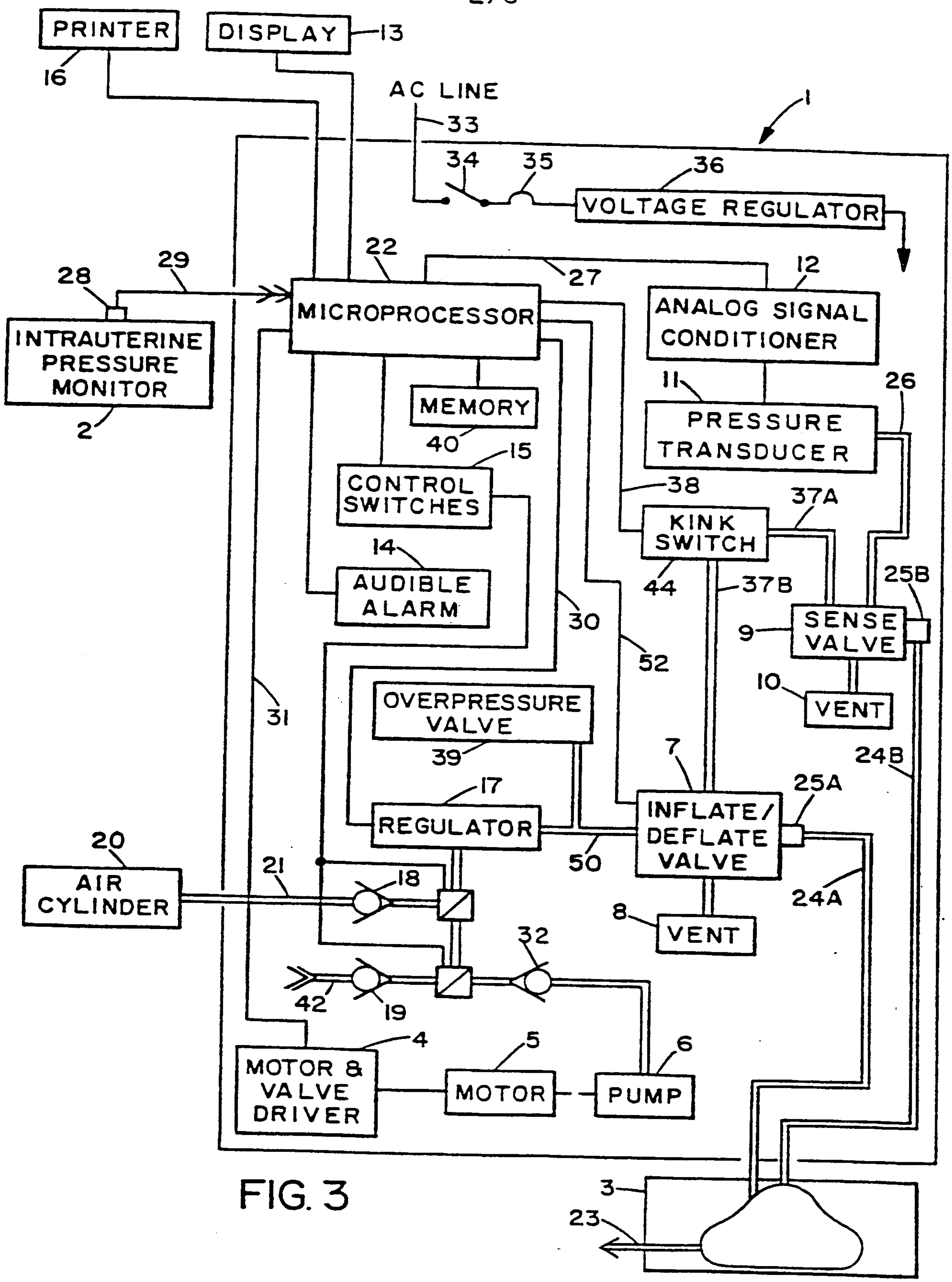
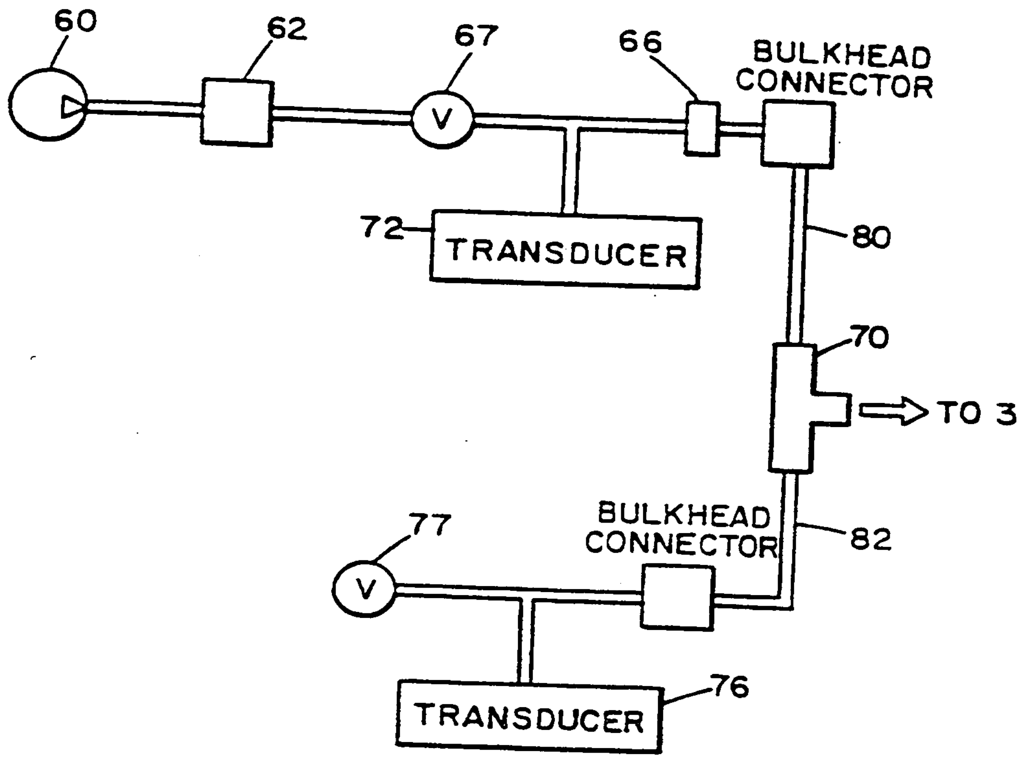

PRINTER
16
DISPLAY
13
AC LINE
33
1
34
35
36
VOLTAGE REGULATOR
22
29
28
27
12
MICROPROCESSOR
ANALOG SIGNAL CONDITIONER
INTRAUTERINE PRESSURE MONITOR
2
11
26
MEMORY
PRESSURE TRANSDUCER
40
15
CONTROL SWITCHES
38
37A
KINK SWITCH
14
AUDIBLE ALARM
44
37B
25B
SENSE VALVE
9
30
52
10
VENT
31
OVERPRESSURE VALVE
39
7
24B
25A
17
REGULATOR
INFLATE/ DEFLATE VALVE
20
50
AIR CYLINDER
21
18
24A
8
VENT
32
42
19
4
5
6
MOTOR & VALVE DRIVER
MOTOR
PUMP
3
23

FIG. 3



60
62
67
66
BULKHEAD CONNECTOR
V
72
TRANSDUCER
80
70
TO 3
77
BULKHEAD CONNECTOR
82
V
TRANSDUCER
76

FIG. 4

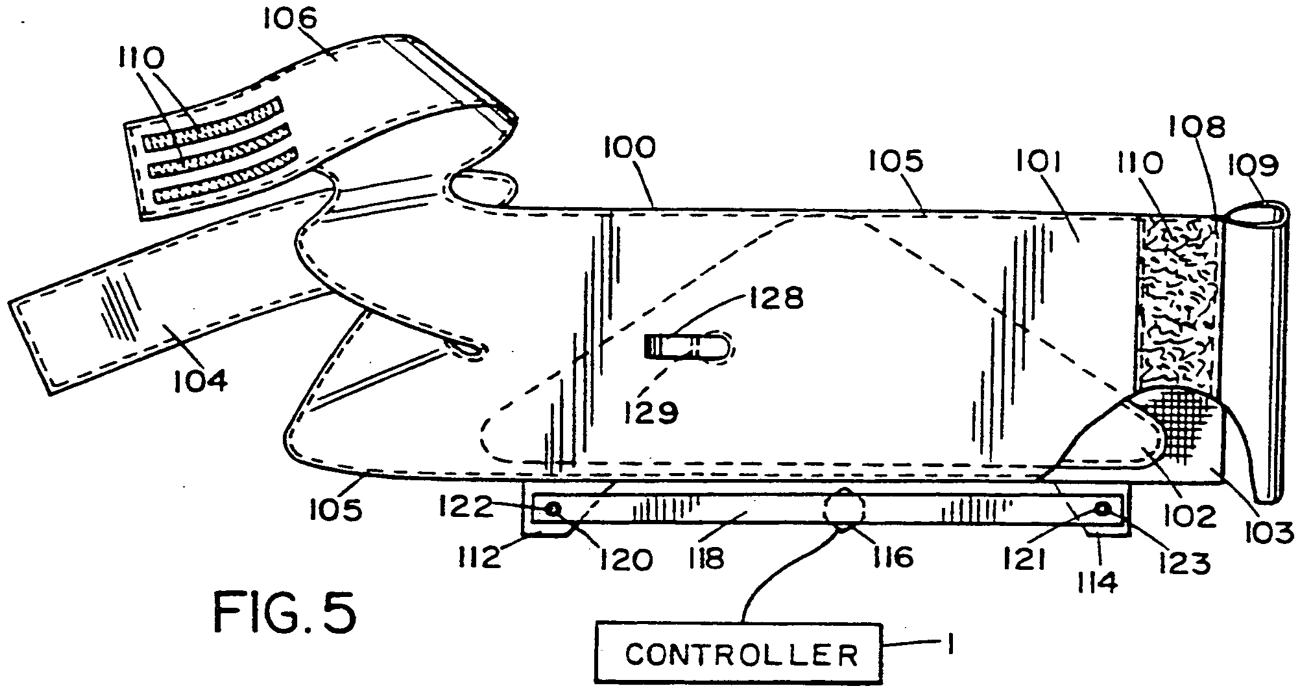


FIG. 5

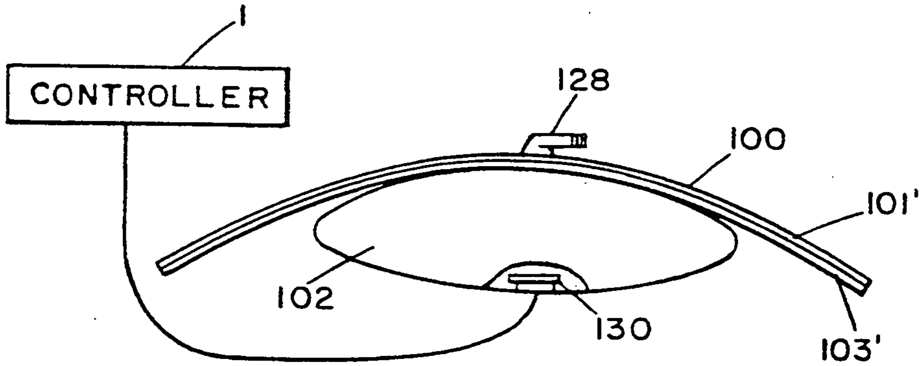


FIG. 6

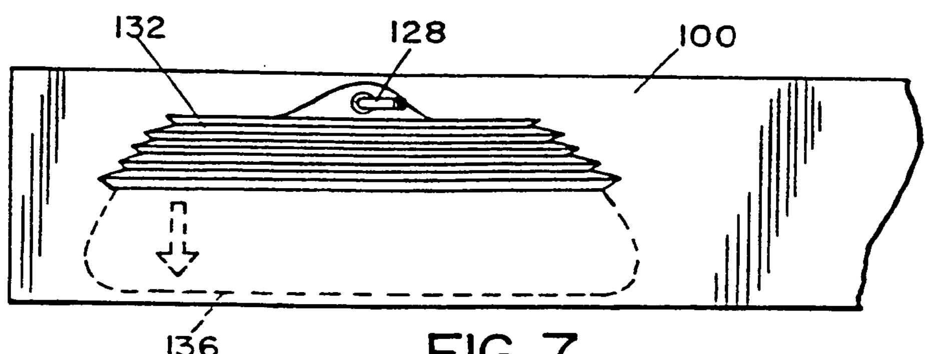


FIG. 7

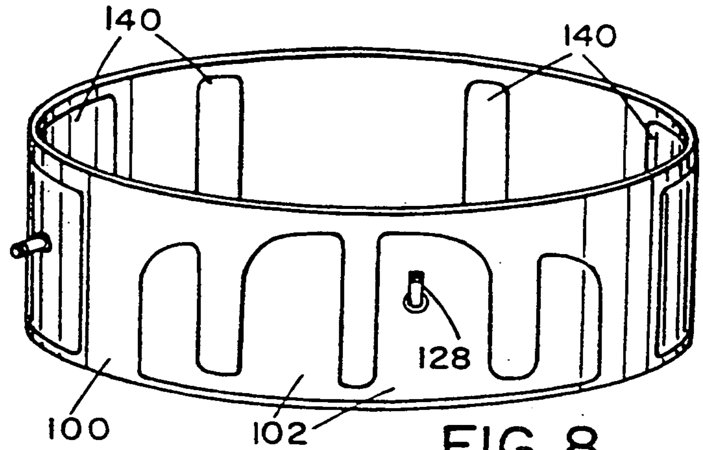


FIG. 8

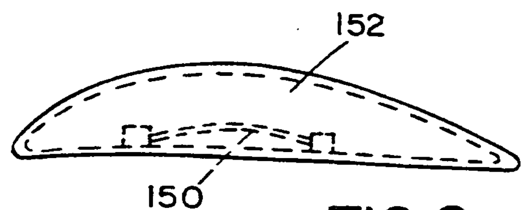


FIG. 9

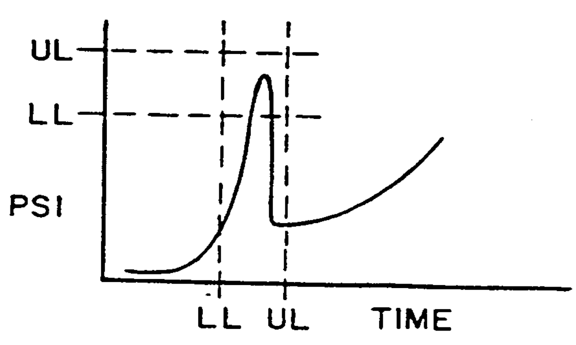


FIG. 10

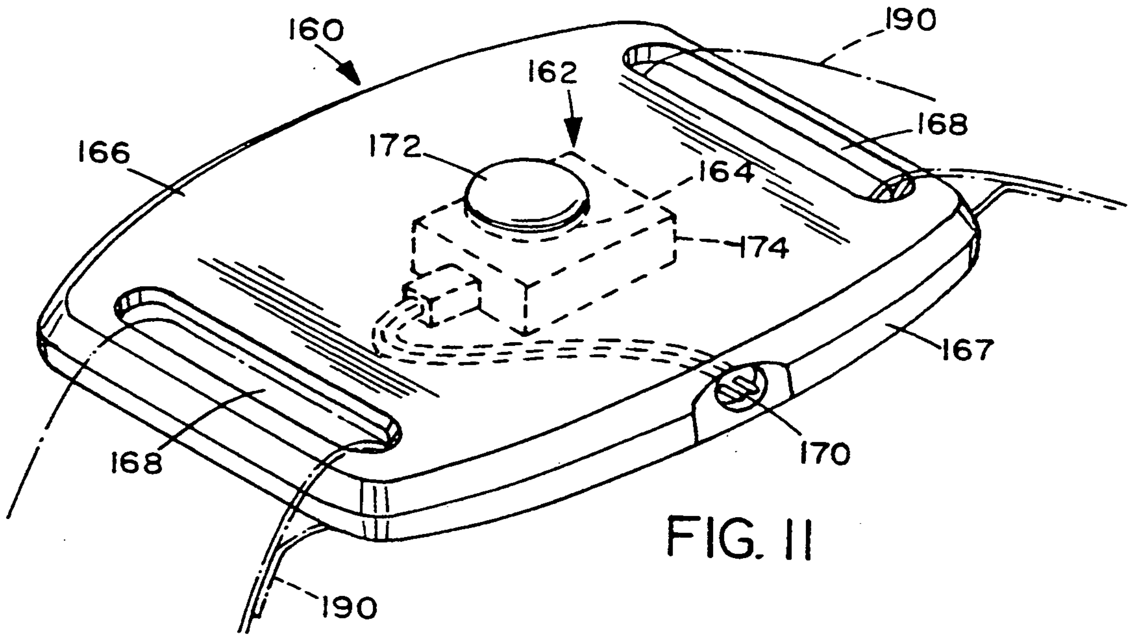
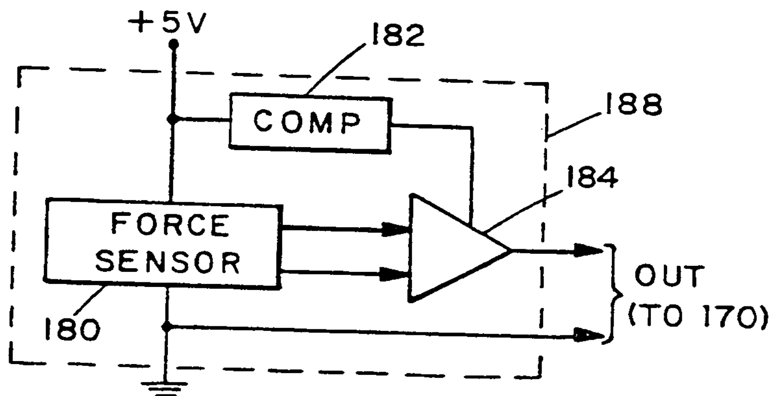


FIG. 11

FIG. 12



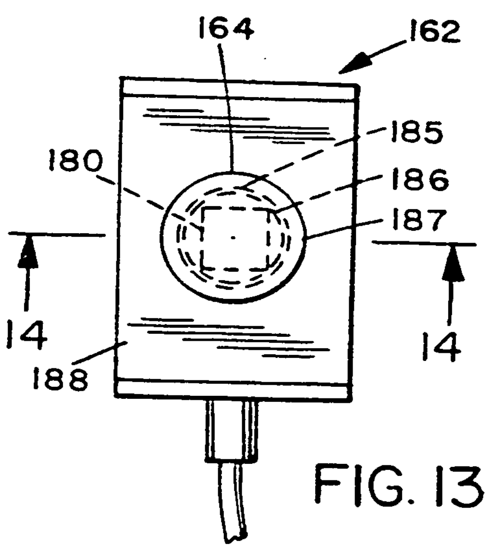


FIG. 13

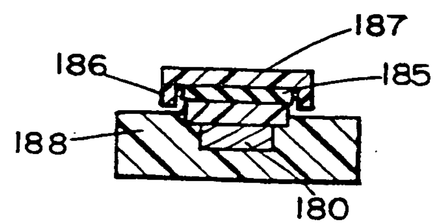


FIG. 14

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/18070

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01L5/00 A61B5/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01L A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 218 972 A (HELTHDYNE) 15 June 1993 see column 3, line 23 - line 31 see column 3, line 44 - line 57; figures 1,2 ---	1-3,6,7 11,19
A	US 3 913 563 A (MEDICAL INSTUMENTS AND TECHNOLOGY) 21 October 1975 see column 4, line 39 - line 56; figure 2 ---	4,5,16, 23-26
A	US 5 645 563 A (NOVATRIX) 8 July 1997 see column 5, line 57 - column 6, line 5 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 1998	18/12/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mielke, W

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/18070

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 673944 B	28-11-1996
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Form PCT/ISA/210 (patent family annex) (July 1992)